

### III. REMARKS

#### A. Telephone Interviews

Applicants, through their undersigned representative, conducted several telephone interviews with the Examiner starting the week of January 17, 2005 through the week of February 7, 2005, concerning this application and the continuation-in-part of this application (Application No. 10/117,030; hereinafter also referred to as "CIP '030 application"). Applicants advised the Examiner that they propose to amend the two applications to overcome obviousness-type double patenting rejections and the issues under 35 USC § 103(c) and 37 CFR § 1.78(c) in both applications. In particular, Applicants said they plan to amend claims in this application so that all claims will be directed to primary cancer, and in claim 52 they plan to delete the recitation "or an individual with a prior resection of early colorectal cancer."

In the CIP '030 application, Applicants said they plan to amend all claims under examination to recite:

- 1) colorectal cancer;
- 2) plasma as the body fluid; and
- 3) total TIMP-1.

Applicants submitted that these amendments would render moot any double-patenting issues and issues under 35 USC § 103(c) and 37 CFR § 1.78(c).

In one of the phone conversations, Dr. Rawlings, the Examiner, advised Applicants that he reviewed Applicants' proposal in detail with Ms. Bonnie Eyler, and it was their opinion that the proposed amendments would overcome the aforementioned issues. Dr. Rawlings asked Applicants to point out support in the specification for the term "benchmark combined perimeter" appearing in some of the claims. Applicants responded that the term "benchmark combined perimeter" is used as a "label" for the combination of the total plasma TIMP-1 concentration of the non-colorectal cancer

population with the free plasma TIMP-1 concentration of the non-colorectal cancer population. Applicants also pointed out that in the same claims in which the term "benchmark combined parameter" appears, a label "combined parameter of the individual" is used to designate the combination of the total concentration of TIMP-1 with the concentration of free TIMP-1 in the plasma sample of the individual, e.g., Claim 41. Dr. Rawlings responded that he may ask Applicants to include a statement in the relevant claims explicitly indicating that the combination of the total plasma TIMP-1 concentration with the free plasma TIMP-1 concentration of the non-colorectal cancer population is referred to as "benchmark combined parameter".

Examiner Rawlings also asked if Applicants would be willing to cancel all withdrawn claims in this application, providing that his final opinion (once he receives a Supplemental Amendment with the amended claims as discussed above) would be that the amended claims are in condition for allowance. Applicants advised that, in such an event, they would authorize cancellation of the withdrawn claims.

**B. ~~Applicants' Amendments Overcome Obviousness-Type Double Patenting and Related Issues~~**

Applicants continue to maintain that their claims, prior to this Amendment, were not directed to the same patentable invention as the claimed invention of the CIP '030 application, at least for the reasons set forth in the Amendment filed on November 2, 2004 (which reasons are incorporated herein by reference). Nonetheless, in the interest of expediting prosecution (and without conceding correctness of any assertions on this issue in the Office Action), Applicants amended their claims in accordance with the telephone interviews. Applicants respectfully submit that these amendments overcome any obviousness-type double patenting rejections and any issues under 35 USC § 103(c) and 37 CFR § 1.78(c).

Claim amendments are supported by the specification, considered as a whole, as exemplified by the following passages: page 3, lines 21-34; page 7, lines 4-10; page 27, lines 18-20; and page 28, lines 1-11.

With regard to the term "benchmark combined perimeter", Applicants respectfully submit that it is clear to a person of ordinary skill in the art from the specification, considered as a whole, that Applicants were in possession of embodiments including that term when the application was filed. Reiterating the telephone interviews, the term "benchmark combined perimeter" is used as a "label" for the combination of the total plasma TIMP-1 concentration of the non-colorectal cancer population with the free plasma TIMP-1 concentration of the non-colorectal cancer population. The label is introduced for the convenience of the reader, and to simplify text of the claims. The combination is explicitly disclosed in the specification, for instance, in Example 9, page 8, lines 26-30, Figure 18, page 32, line 9 - page 34, line 9. As discussed above, in the same claims in which the term "benchmark combined parameter" appears, a label "combined parameter of the individual" is used to designate the combination of the total concentration of TIMP-1 with the concentration of free TIMP-1 in the plasma sample of the individual. For example, see Claim 41, subsections b) and d). Applicants respectfully submit that the term "benchmark combined perimeter" does not constitute new matter.

Applicants also cancelled several other claims and amended some additional claims. Applicants reserve all their rights to pursue the subject matter of the cancelled claims in this or any related applications. Applicants plan to add the cancelled claims directed to the screening of metastatic breast cancer to the CIP '030 application.

#### **C. ~~Information Disclosure Statements~~**

Applicants wish to point out that on November 8, 2004, they filed a Supplemental Information Disclosure Statement. Applicants respectfully request acknowledgement of receipt by the Patent Office of that Supplemental IDS, and an indication that it was considered by the Examiner.

#### **D. ~~Request for Allowance~~**

In view of the above, Applicants respectfully submit that all claims are in condition for allowance, an indication of which is solicited. In the event any outstanding

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issues remain, Applicants would appreciate the courtesy of a telephone call to the undersigned counsel to resolve any such issues in an expeditious manner and place the application in condition for allowance.

If any fees are necessitated by the filing of this Amendment, please charge the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,  
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